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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/530,003      | 04/21/2000  | HARRY ZSCHEEG        | A0008/7000          | 8603             |

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EXAMINER

WOO, JULIAN W

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

3731

DATE MAILED: 04/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |  |                     |  |
|------------------------------|------------------------|--|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> |  | <b>Applicant(s)</b> |  |
|                              | 09/530,003             |  | ZSCHEEG, HARRY      |  |
|                              | <b>Examiner</b>        |  | <b>Art Unit</b>     |  |
|                              | Julian W. Woo          |  | 3731                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 06 September 2000.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-13,19-22 and 27-45 is/are pending in the application.
- 4a) Of the above claim(s) 12,13,19-22 and 31-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-11 and 27-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 21 April 2000 is: a) ☒ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)              | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other:  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claims 1, 3-11, and 27-30, drawn to an expandable stent, classified in class 623, subclass 1.18.
- II. Claims 12, 13, 19-22, and 31-45, drawn to a production process for a stent, classified in class 219, subclass 121.67.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made.

The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the stent as claimed can be made by the process of molding, by the welding of wires, or by chemical etching.

2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

3. During a telephone conversation with Arthur Brookstein, Reg. No. 22958, on March 27, 2002, a provisional election was made with traverse to prosecute invention I, claims 1, 3-11, and 27-30. Affirmation of this election must be made

by applicant in replying to this Office action. Claims 12, 13, 19-22, and 31-45 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### ***Specification***

4. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

5. The disclosure is objected to because of the following informality: On pages 3, 6, and 7, references to the claims, in the "Summary of the Invention," should be deleted, since the invention should be independently described before claims are made. Appropriate correction is required.

### ***Drawings***

6. Figures 1 and 2 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 6, 8-11, and 27-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect

to base claim 6, line 2, "wall cents" is not defined. (If –wall segments— was meant: What aspect of a segment has the "width" as claimed? Is it the width measured in the stent's expanded state or unexpanded state; or is the width measured at an intersection?) With respect to independent claim 27, "a stent delivery system" is not positively recited in the body of the claim as part of the "combination" with the stent. Also with respect to claim 29, line 1, "the application system" lacks antecedent basis. Also with respect to claim 30, line 1, "A process" lacks antecedent basis.

### ***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 3, 8-10, and 27-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Lau et al. (5,514,154). With respect to claims 1, 3, and 27, Lau et al. disclose in figures 1-5, an expandable stent (10) with an elastic tubular lattice structure having first and second end zones, a longitudinal direction, a radial direction, wall segments with intersections (at 13), and wall segments with interrupted intersections (at portions of 12), where expansion of the wall segments is formed by an arcuate curvature. With respect to claims 8-10, col. 6,

lines 61-63 disclose that the stent consists of a metallic, shape memory alloy or a nickel-titanium alloy. With respect to claims 28 and 29, col. 4, lines 30-64 disclose a delivery system with a balloon dilation catheter applied with the Seldinger technique.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 4, 5, 11, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lau et al. Lau et al. disclose the stent and stent delivery system substantially as claimed, but do not disclose stent wall intersections interrupted at substantially two thirds of all intersections, aperture widths of maximally 9 mm when the stent is expanded, and alloy moieties as claimed. Nevertheless, it would have been a matter of design choice to one of ordinary skill in the art at the time the invention was made, to configure the stent as

claimed, and it would be a matter of design choice to manufacture a stent with alloy moieties as claimed. The choices would be dependent upon the conditions in which the stent would be used. Various vascular applications, for instance, require stents of various configurations, dimensions, and resilient materials of various compositions.

14. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lau et al. in view of Fogarty et al. (EP 792627). Lau et al. disclose the stent substantially as claimed, but do not disclose a wall thickness between 0.2 mm and 0.3 mm. Fogarty et al. teach, in col. 10, lines 14-18, a stent with a wall thickness between about 0.1 mm and 0.5 mm. It would have been obvious to one having ordinary skill in the art, at the time the invention was made, in view of Fogarty et al., to modify the stent of Lau et al., so that it has a wall thickness within the range as claimed. Such a stent would have the mechanical strength for reinforcing an aortic aneurysm.

### ***Conclusion***

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Corso, Jr. et al. (5,913,897), Johnson (5,972,027), and Kim (6,270,524) teach stents having wall segments with and without intersections.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached at (703) 308-2496.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703)308-0858. The FAX number is (703)872-9302.

A handwritten signature in black ink, appearing to read 'J Woo', with a stylized flourish extending from the end.

Julian W. Woo  
Patent Examiner

March 27, 2002